

Appl. No. : 10/663,362
Filed : September 16, 2003

REMARKS

The foregoing amendments and the following remarks are responsive to the October 19, 2006 Office Action. Claims 1, 2, and 4-24 remain pending in the present application. Claim 1 has been amended, Claim 3 has been cancelled, and Claims 17-24 have been withdrawn from consideration.

In response to the Office Action mailed October 19, 2006, Applicants respectfully request the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

Reed Does Not Disclose the Fluid Medication Delivery Device Recited By Claims 1, 3-5, 7-9, and 12-14

Claims 1, 3-5, 7-9, and 12-14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Reed, Jr. (U.S. Patent No. 5,827,530) ("Reed"). Applicants respectfully traverse the present rejection. However, to expedite the prosecution of the present application, Applicants have amended Claim 1 and cancelled Claim 3. Applicants also expressly reserve the right to further prosecute the original versions of Claims 1-6 through continuation practice.

Claims 1, 4, and 5

Reed discloses a fillable patch for dermal or transdermal delivery. According to Reed, the patch comprises a loading port 32, through which medication can be injected by a hypodermic needle. The loading port 32 is comprised of a rubber septum which can seal when the needle is withdrawn. In other embodiments, the hypodermic needle punctures a hole 49 in the septum, through which medication can be introduced. The fillable patch relies upon the rubber septum to reseal after removal of the needle to prevent leakage. Reed does not disclose a fluid inlet comprising a one-way valve configured to permit fluid entry into a fluid reservoir and prevent fluid from exiting the fluid reservoir through the fluid inlet.

By contrast, Amended Claim 1 recites: (emphasis added)

A fluid medication delivery device, comprising:

a fluid impermeable layer;

a fluid semi-permeable layer, said semi-permeable layer and said impermeable layer cooperating to define a space therebetween, said space defining a fluid reservoir of said delivery device, said semi-permeable layer and said impermeable layer having a continuous seal therebetween to define a periphery of said fluid reservoir;

a fluid inlet communicating with said fluid reservoir, said fluid inlet comprising a valve configured to permit fluid entry into said fluid reservoir, said fluid inlet adapted to permit said delivery device to be selectively connectable to a supply of fluid, **wherein said valve comprises a one-way valve configured to permit fluid to enter said fluid reservoir and preventing fluid from exiting said fluid reservoir through said fluid inlet; and**
wherein a fluid is diffusible across said semi-permeable layer in response to a pressure imparted on said fluid.

Thus, the fluid medication delivery device of amended Claim 1 recites, among other recitations, a one-way valve to introduce medication to the fluid reservoir. A one-way valve functions differently than a rubber septum. As one non-limiting example, a rubber septum can leak fluid when an internal reservoir is filled to a capacity such that the fluid exerts an outward pressure on the septum, unlike a one-way valve.

For at least this reason, Applicants submit that Reed fails to disclose each and every element recited by amended Claim 1. Accordingly, Applicants respectfully request the Examiner withdraw the rejection of Claim 1 and pass this claim to allowance.

Additionally, Applicants submit that Claims 4 and 5 also define over the cited reference, not only because they depend from Claim 1, but also on their own merit. Accordingly, Applicants respectfully request the Examiner withdraw the rejection of Claims 4 and 5 and pass these claims to allowance.

Claims 7-9 and 12-14

In Figure 2, Reed discloses a fillable patch comprising a backing layer 22, a fillable reservoir 24, a diffusion membrane 16, a skin-contact adhesive layer 12, and a release liner 14. Reed, col. 3, lns. 34-67. Thus, Reed discloses a fillable patch with a fluid-impermeable layer on one side, a skin-adhesion layer on the other, and a diffusion layer therebetween. Reed does not disclose a fillable patch comprising a fluid impermeable pouch having first and second opposing walls, the first wall and second wall defining a space between them.

By contrast, Claim 7 recites: (emphasis added)

A fluid medication delivery device, comprising:
a fluid impermeable pouch having first and second opposing walls, said first wall and said second wall defining a space therebetween, said space defining a fluid reservoir of said delivery device, said second wall including a plurality of openings therethrough defining a diffusion area of said delivery device;

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a fluid inlet communicating with said fluid reservoir, said fluid inlet comprising a valve configured to permit fluid entry into said fluid reservoir, said fluid inlet adapted to permit connection to a supply of fluid; and

a fluid semi-permeable layer covering at least said diffusion area of said delivery device, said semi-permeable layer being configured such that fluid within said fluid reservoir must pass through said semi-permeable layer before exiting said delivery device.

Claim 7, recites, among other recitations, “a fluid impermeable pouch having first and second opposing walls, said first all and said second wall defining a space therebetween.” Thus, Reed fails to disclose the fluid medication delivery device recited by Claim 7. Accordingly, Applicants respectfully request the Examiner withdraw the rejection of Claim 7 and pass this claim to allowance.

Additionally, Applicants submit that Claims 8, 9, and 12-14 also define over the cited reference, not only because they depend from Claim 7, but also on their own merit. Accordingly, Applicants respectfully request the Examiner withdraw the rejection of Claims 8, 9, and 12-14 and pass these claims to allowance.

Claims 6, 15, and 16 are not Obvious over Reed in View of Meconi

Claims 6, 15, and 16 stand rejected under 35 U.S.C. § 103(a) as being obvious over Reed in view of Meconi *et al.* (U.S. Patent No. 5,770,220) (“Meconi”). Applicants respectfully traverse the present rejection.

The Examiner argues that Reed discloses the fluid medication delivery device recited by Claim 6, 15, and 16, excepting the disclosure of materials and a semi-permeable layer that is external to the fluid pouch.

Claim 6

Applicants submit that Claim 6 defines over Reed as described above. Meconi fails to rectify the failure of Reed to disclose, among other elements, “a one-way valve configured to permit fluid to enter said fluid reservoir and preventing fluid from exiting said fluid reservoir through said fluid inlet.” Accordingly, Applicants respectfully request the Examiner withdraw the rejection of Claim 6 and pass this claim to allowance.

Claims 15 and 16

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Applicants submit that Claims 15 and 16 define over Reed, as described above. Meconi fails to rectify the failure of Reed to disclose, among other elements, "a fluid impermeable pouch having first and second opposing walls, said first all and said second wall defining a space therebetween." Accordingly, Applicants respectfully request the Examiner withdraw the rejection of Claims 15 and 16 and pass these claims to allowance.

Claims 2 and 10-11 are not Obvious over Reed

Claims 2, 10, and 11 stand rejected under 35 U.S.C. § 103(a) as being obvious over Reed. Applicants respectfully traverse the present rejection.

The Examiner argues that Reed discloses the claimed inventions except for specific material dimensions. As explained above, Reed fails to disclose the fluid medication delivery device recited by Claims 1 and 7.

Claim 2 depends from amended Claim 1. Claims 10 and 11 depend from Claim 7. Applicants submit that Claims 2, 10, and 11 define over the cited reference not only because they depend from Claims 1 and 7, but also on their own merit. Accordingly, Applicants respectfully request the Examiner withdraw the rejection of Claims 2, 10, and 11, and pass these claims to allowance.

SUMMARY

For the reasons described above, Applicants respectfully request the Examiner withdraw the rejection of the claims and pass Claims 1-16 to allowance.

The undersigned has made a good faith effort to respond to all of the rejections and objections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve such issue promptly.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: February 8, 2007

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